Proposed Course Outline – NCSU Regulatory Affairs for Crop Protection

All Classes 406 Mann from 3 to 5:45 except Day 14

Day 1 August 22-multiple speakers

Course introduction **(Keith Edmisten)**

Introduction

a. Importance of crop protection (**Keith Edmisten**)
b. Different technologies currently available (**Keith Edmisten**)
c. Technical process vs political issues (**Jason Delborne**)
d. Societal need/ public need (**Jason Delborne**)
e. Benefits document (part of registration) (**Chris Hofelt**)

2. Summary of Discovery to Market (**Chris Hofelt**)
    a. Screening (bioefficacy)
    b. Safety studies
    c. Formulation and Manufacturing
    d. Commercialization

Day 2 August 29 – (Scott Shore)

3. Overview of laws, regulations and agencies (deep dive in future lecture)
    a. EPA, FDA, USDA
    b. FIFRA
    c. 7 CFR Part 340
    d. FFDCA
    e. OSHA, HazCom, WPS, etc.
4. Deeper dive into laws that govern regulation, what are they and how they came about.
    a. Local (top 4 are very relevant to biotech regulation, bottom 5 more relevant to crop protection products)
        i. Plant Protection Act
        ii. Federal Food, Drug, and Cosmetic Act
        iii. Federal Insecticide, Fungicide and Rodenticide Act
        iv. National Environmental Policy Act
        v. Endangered Species Act
        vi. Clean Water Act
        vii. Toxic Substances Control Act
        viii. HazCom and WPS
        ix. State laws (how state laws may differ)
    b. Global

i. Convention on Biodiversity
ii. Cartagena Protocol on Biosafety
iii. Nagoya Protocol
iv. EU and EFSA issues

Day 3 September 12 (lecturer 1) 3pm to 3:50

5. Traits 101 **(Ralph Dewey) (Ali Scott from Bayer has offered to help)**
    a. What is a GMO?
    b. How does a transformation happen
    c. Where does a gene come from (donor organisms)?
    d. Terminology
    e. Stacks (and regulatory issues)
    f. Comparison with conventional breeding/mutational/gene editing
    g. Future techniques

Day 3 September 12 (lecturer 2) 3:55 to 4:45

6. Conventional pesticides 101 **(Travis Gannon) (Mark Parrish from Bayer has offered to help)**
    a. What is a pesticide
    b. Discovery
    c. Screening
    d. Mode of actions
    e. Targets (pest)

Day 3 September 12 (lecturer 3) 4:55 to 5:45

7. Biological-based pesticides 101 **(George Fountas) (Nick Wright from Bayer has offered to help)**
    a. Biologicals sources
    b. How is a biological manipulated in the lab?
    c. Formulating/fermentation
    d. Biostimulants, biofertilizers, biopesticides
    e. Differences from conventional pesticides
    f. Positioning of biologicals in organic ag and IPM

Days 4 and 5 September 19 & 26 (Volker Bornemann & Friends) (Charlotte Sanson **from Bayer has offered to help)**

8. Conventional pesticide regulatory affairs (and biological regulatory affairs)
    a. Technical proof of concept (phases 0 and 1)
        i. Laboratory safety (OSHA HazCom)
        ii. Efficacy studies + Field performance
        iii. Phytotoxicity

iv. Persistence /stability
v. Theoretical toxicity modeling

b. Commercial proof of concept (phase 2)
   i. Formulation
   ii. Toxicology
   iii. Ecotoxicology
   iv. Non-target plants/animals
   v. Environmental Fate
   vi. Metabolism
   vii. Product chemistry
   viii. Risk assessment

c. Development (phase 3)
   i. Regulatory studies compilation
   ii. Submission of dossier
   iii. Life-cycle management (patent lifespan, strategy, etc.)
   iv. Label uses and efficacy claims
   v. Field testing and selection of final product (formulation, etc.)

d. Commercial (phase 4)
   i. Label amendments
   ii. Adverse effect reporting
   iii. Marketing/ Post-market conditional registrations
   iv. Resistance monitoring & best management practices
   v. IR4 (maybe off topic)
   vi. Manufacturing aspects
   vii. State registration
   viii. Stewardship (product, distribution channel, grower)
   ix. Food chain/ international trade (note: there will be a full lecture on this later)

Days 6 and 7 October 3 & 10 (Laura Privalle & Friends) (Dean Bushey, Ali Scott, Michael Weeks from Bayer have offered to help)

9. Traits regulatory affairs
   a. Technical Proof of Concept (phase 0 and 1)
      i. Early discovery (genes)
      ii. Efficacy and field trials
      iii. Field trial compliance (continues through phase 3)
      iv. Gene flow containment
      v. Permits/movement/detection
      vi. Biosafety
      vii. Bioinformatics

viii. Preliminary safety assessment

b. Commercial proof of concept (phase 2)
    i. Efficacy studies and field performance
    ii. Transformation
        1. Elite event selection
        2. Molecular vs breeding stacks
        3. Site directed transformation, NGS,
    iii. Protein regulation dossier
        1. Protein characterization
        2. Mammalian toxicology/allergenicity
        3. Ecotoxicology
            a. Non-target plants/animals
c. Development (phase 3)
    i. Event Regulatory dossier
    ii. Trait introgression
    iii. Performance/demonstration trials
    iv. International registration issues/process
d. Commercial (phase 4)
    i. Regulatory registration/fed/states (need to expand section)
    ii. Co-registration of herbicides/ companion technology
    iii. Stewardship
    iv. Seed chain
    v. Performance trials
    vi. Insect resistance management
    vii. Food chain/ international trade (note: there will be a full lecture on this later)

Day 8 October 17 (Katie Davis)

10. Understanding and translating environmental and human safety studies, product characterization, etc.
    a. This item and number 2 above would be the week before the mock regulatory package presentations
11. Presentation skills
    a. Maybe present a proposed regulatory package to a mock USDA, EPA, or FDA panel of risk assessors as student groups
12. Negotiating skills
    a. Could potentially be tied into the proposed presentation skills activity
    b. Stakeholders
    c. Regulatory officials
13. Legal aspects (IP and legal) **(Kristine Kring)**
    a. Patent protection
    b. Product (technology) liability

c. Lifecycle management
d. Proprietary regulatory studies (data compensation)
e. Anti-trust laws
f. Complaints
g. Ethics/compliance
h. Business confidentiality

Day 9 October 24 (Damian Shea)

14. Toxicology 101 for compliance personnel
    a. Acute vs Chronic
    b. Hazard vs risk
    c. Toxicological endpoints
    d. LD50 / LC50
    e. GLP

Day 10 October 31 (Scott Kohne)

15. Global and 'big picture' topics (lecture would be cross-technology)

    a. Trade flow of agricultural products, key import/export markets

    b. Global regulatory frameworks and conventions

        1. Codex Alimentarius (MRL setting)

        2. Convention on Biological Diversity (Cartagena Protocol, Nagoya Protocol, etc.)

        3. Asynchronous authorizations (LLP/AP issues and proposals)

    c. Overview of key (US-centric) national and regional non-US regulatory systems and issues (relate to trade flow)

        1. EU (trait and crop protection)

        2. China

        3. Other key countries/regions

Day 11 November 7 (Scott Kohne)

17. Local issues discussion and debate (cross-technology)

    a. Secondary non-regulatory standards lecture

b. Agricultural coexistence (discussion or debate)

c. Food labeling laws and voluntary systems (discussion or debate)

Day 12 November 14 (Michael Weeks)

16. Field research compliance
    a. This should come after the overview of the laws and regulations
    b. Could demonstrate how a biotechnology permit is put together and the process for submitting and subsequent reporting requirements
    c. Isolation,
    d. in-season and post-harvest monitoring
    e. Movement and import of biotechnology products
    f. Quality management and identity preservation tactic
    g. Audits and field inspection process

Day 13 November 21 (Iian Kelly)

17. The future and regulatory for new (or undiscovered) technologies
    a. Innovations and technology
    b. Challenges
    c. Opportunities
    d. Outlook

Day 14 November 28 (Chris Hofelt)

Review: Life of a molecule

Day 15 December 9 (1 pm to 4 pm)

Careers in regulatory science review: **(Bob Graney)**

Careers in regulatory affairs panel. **(Chris Hofelt, Allen James, Alan Ayers)**